consultation and technical assistance to a wide range of researchers and institutions at the state, national, and international levels, addressing the definitions, needs, and uses for national and subnational health interview statistics and data.

Delete in their entirety the title and functional statement for the *Data Analysis Branch (CS74) and insert the following:*

Data Analysis and Quality Assurance Branch (CS74). (1) Conducts research and analysis on topics relevant to public health using National Health Interview Survey (NHIS) data; (2) plans, develops, and implements analytic techniques and guidelines to assure data quality standards for Division surveys and supplements; (3) prepares scientific papers and presentations on the health status of the population, broad health trends, and characteristics of persons with health problems using data from the NHIS; (4) converts identified health interview statistics data needs into research, development, and evaluation activities; (5) conducts descriptive analyses as well as multivariate analyses that integrate data across multiple surveys or data sets; (6) administers analytic and scientific peer review of manuscripts produced from data collected in the Division's programs; (7) develops and implements a data dissemination plan to address needs of researchers; (8) serves as the NCHS resource on health interview survey data and their use in assessing the prevalence and incidence of disease and associated disabilities, health status, health related behaviors, health insurance status, and other health and well-being related topics; (9) provides interpretations and recommendations regarding public health issues as a result of data analyses from the NHIS; and (10) provides consultation, technical assistance, and liaison to academia, other research groups, and State, Federal, and international entities concerning the development, uses, and dissemination of health interview survey data.

Delete in their entirety the title and functional statement for the *Special Population Surveys Branch (CS75).*

Dated: June 6, 2004.

William H. Gimson,

Chief Operating Officer, Centers for Disease Control and Prevention (CDC).

[FR Doc. 04–14006 Filed 6–21–04; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0079]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Specific Requirements on Content and Format of Labeling for Human Prescription Drugs of Geriatric Use Subsection in the Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 22, 2004.

ADDRESSES: The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Specific Requirements on Content and Format of Labeling for Human Prescription Drugs of Geriatric Use Subsection in the Labeling—(OMB Control Number 0910–0370)—Extension

Section 201.57(f)(10) (21 CFR 201.57(f)(10)) requires that the ''Precautions'' section of prescription drug labeling must include a subsection on the use of the drug in elderly or geriatric patients (aged 65 and over). The information collection burden imposed by this regulation is necessary to facilitate the safe and effective use of prescription drugs in older populations. The geriatric use subsection enables physicians to more effectively access geriatric information in physician prescription drug labeling.

Section 201.57(f)(10) requires that a specific geriatric indication, if any, that is supported by adequate and well-controlled studies in the geriatric population must be described under the ''Indications and Usage'' section of the labeling, and appropriate geriatric dosage must be stated under the ''Dosage and Administration'' section of the labeling. The ''Geriatric use'' subsection must cite any limitations on the geriatric indication, need for specific monitoring, specific hazards associated with the geriatric indication, and other information related to the safe and effective use of the drug in the geriatric population. The data summarized in this subsection of the labeling must be discussed in more detail, if appropriate, under ''Clinical Pharmacology'' or the ''Clinical Studies'' section. As appropriate, this information must also be contained in ''Contraindications,'' ''Warnings,'' and elsewhere in ''Precautions.'' Specific statements on geriatric use of the drug for an indication approved for adults generally, as distinguished from a specific geriatric indication, must be contained in the ''Geriatric use'' subsection and must reflect all information available to the sponsor that is relevant to the appropriate use of the drug in elderly patients. These statements are described further in § 201.57(f)(10).

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
201.57(f)(10) NDAs	73	1.48	108	8	864

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
201.57(f)(10) ANDAs	96	4.67	449	2	898
Total					1,762

[1] There are no capital costs or operating and maintenance costs associated with this collection.

In the **Federal Register** of March 9, 2004 (69 FR 11021), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Dated: June 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–14078 Filed 6–21–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

International Workshop on Minor Use and Minor Species: A Global Perspective; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''International Workshop on Minor Use and Minor Species (MUMS): A Global Perspective.'' The workshop is the result of a partnership between FDA's Center for Veterinary Medicine (CVM) and the U.S. Department of Agriculture's (USDA's) minor use animal drug program, the National Research Support Project #7 (NRSP–7). The purpose of the workshop is to assemble international expertise to discuss the global pursuit of drug approvals for MUMS. The workshop is planned to provide several ''forums'' for discussion of the global perspectives of drug needs and drug approvals for minor species and minor uses. Areas to be discussed include data requirements for MUMS drug approvals (effectiveness, target animal safety, human food safety, environmental safety, etc.), the classification of minor species, and husbandry practices in the various regions of the world. Anticipated outcomes of the workshop include methods and strategies to improve cooperation and coordination of national and regional programs to maximize MUMS drug approvals internationally.

Date and Time: This 2-day public workshop will be held on October 7, 2004, from 8:30 a.m. to 5:45 p.m., and on October 8, 2004, from 8:30 a.m. to 12:15 p.m. Registration opens at 7:30 a.m. each day.

Location: The public workshop will be held at the DoubleTree Hotel, Plaza Room III, 1750 Rockville Pike, Rockville, MD.

The DoubleTree Hotel is accessible via the Washington, DC Metro Transit System, Red Line, and is located next to the Twinbrook Metro Station. The hotel is a short walk from the station.

Contact: Margaret Oeller, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–3067, FAX: 301–827–4572, or e-mail: *moeller@cvm.fda.gov*.

Registration: Registration forms for the workshop are available from the CVM/FDA's Web site and should be completed online. If a paper copy is needed, please contact Anna Roy, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–2957, FAX: 301–827–4572, or e-mail: *aroy@cvm.fda.gov* by Wednesday, October 6, 2004. There is no registration fee for the public workshop. Because seating is limited, we recommend early registration.

If you need special accommodations due to a disability, please contact Anna Roy at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: FDA's CVM, in partnership with the USDA's National Research Support Project #7 (NRSP–7), will convene a public workshop entitled ''International Workshop on Minor Use and Minor Species (MUMS): A Global Perspective.'' International representatives have been invited to speak on pertinent issues relating to product approvals for MUMS from their respective countries.

There will be an opportunity to raise additional questions and issues for discussion during open public comment periods during each day of the workshop. Prior to the meeting, the draft agenda for this public workshop will be posted on CVM's Web site at *http://www.fda.gov/cvm/default.html* and on the NRSP–7 Web site at *http://www.nrsp7.org* (FDA has verified the Web site address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**).

Transcripts: Transcripts of the workshop will be posted on the CVM Web site at *http://www.fda.gov/cvm/default.html*. Written copies of the transcript may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, after the public workshop, at a cost of 10 cents per page.

Questions about the workshop may be directed to Margaret Oeller, CVM, at 301–827–3067 or *moeller@cvm.fda.gov* by Tuesday, October 5, 2004.

Dated: June 15, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–14015 Filed 6–21–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D–0785]

Guidances for Industry on Medical Imaging Drug and Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of three guidances for industry on ''Developing Medical Imaging Drug and Biological Products.'' These guidances are intended to assist developers of medical imaging drug and biological products (medical imaging agents) in planning and coordinating their clinical investigations and preparing and submitting